**PIN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | | |
|---|---|---|
| **MOSKOWITZ FAMILY LLC** | : | |
| | : | **CIVIL ACTION** |
| ***Plaintiff*,** | : | |
| | : | |
| **v.** | : | **No. 20-3271** |
| | : | |
| **GLOBUS MEDICAL, INC.** | : | |
| | : | |
| ***Defendants*.** | : | |

**MEMORANDUM OPINION**

**Goldberg, J.** **December 22, 2022**

Plaintiff Moskowitz Family LLC ("Plaintiff") holds several patents pertaining to spinal implants designed to reduce adverse outcomes in spinal fusion patients. Plaintiff's inventions include minimal impaction, steerable, and custom-fit intervertebral implants that minimize musculoskeletal disruption and nerve root retraction during and after the procedure. Defendant Globus Medical, Inc. ("Defendant") is another spinal fusion company that sells intervertebral spinal implants. Plaintiff accuses Defendant's products of directly and indirectly infringing on Plaintiff's patents.

Defendant moves for partial summary judgment on Plaintiff's direct infringement and indirect infringement claims. For the following reasons, I will grant Defendant's Motion and enter judgment on its behalf regarding the direct infringement claims but will deny Defendant's Motion on induced infringement.

## I. GENERAL FACTUAL BACKGROUND

As explained during the claim construction hearing, the human spine is composed of vertically arranged bones called vertebrae, which are separated by cartilaginous intervertebral

discs. The vertebrae are divided into three portions: (1) the uppermost seven are called the cervical spine; (2) the middle twelve are called the thoracic spine; and (3) the bottom five are called the lumbar spine. Two pedicle bones dorsally extend from each vertebra and form an arch that protects the spinal cord.

In some individuals, the cartilaginous disc between vertebrae may wear, causing pain and pressure on the spinal cord. For such individuals, spinal fusion surgery may offer relief. This procedure permanently connects two or more spinal vertebrae to improve spinal stability, correct deformations, and reduce pain. This procedure can also result in some adverse patient outcomes such as high-impaction, neural or vascular injury, esophageal injuries, excessive blood loss, prolonged surgical duration, prolonged recovery, and incomplete return to work results. These adverse events may be the result of static and non-expandable implants, misplaced implants, and implant pull-out after surgery.

Plaintiff sought to invent minimally invasive spinal implants designed to reduce these adverse outcomes. From January 15, 2013 through November 19, 2019, the United States Patent and Trademark Office ("PTO") issued to Plaintiff the eight patents at issue. These patents are directed to intervertebral spine implant screws, staples, and expandable implant systems. U.S. Patent Nos. 8,353,913 (the "'913 patent"), 110,307,268 ("'268 patent"), and 10,478,319 (the "'319 patent") are for tools used to manipulate and insert spacers into a disc space between two vertebral bodies to facilitate bone and screw fusion. U.S. Patent No. 9,889,022 (the "'022 patent") is for an intervertebral screw guide and fixation apparatus for insertion into a disc space between two vertebrae to encourage bone and screw fusion. U.S. Patent No. 10,028,740 (the "'740 patent") claims a "curvilinear nail screw," a holding structure implanted into a vertebra and around the pedicle bones to avoid penetrating them. U.S. Patent No. 10,251,643 (the "'643 patent") relates

to an intervertebral mechanism that expands between vertebral bodies and engages vertebral endplates to keep the mechanism in place. U.S. Patent No. 10,076,367 (the "'367 patent") is for a bidirectional system inserted between vertebrae to facilitate their linking and fusion. Finally, U.S. Patent No. 10,376,386 (the "'386 patent") claims a spinal staple with a curved based and ridged spikes that hinder the staple's removal.

On November 20, 2019, Plaintiff sued Defendant alleging both direct and indirect infringement of these various patents.

## II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 states, in pertinent part:

> A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. The court should state on the record the reasons for granting or denying the motion.

Fed. R. Civ. P. 56(a). "Through summary adjudication, the court may dispose of those claims that do not present a 'genuine dispute as to any material fact' and for which a jury trial would be an empty and unnecessary formality." Capitol Presort Servs., LLC v. XL Health Corp., 175 F. Supp. 3d 430, 433 (M.D. Pa. 2016). A factual dispute is "material" if it might affect the outcome of the suit under the applicable law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). An issue is "genuine" only if there is a sufficient evidentiary basis that would allow a reasonable fact-finder to return a verdict for the non-moving party. Id.

The initial burden is on the moving party to adduce evidence illustrating a lack of genuine, triable issues. Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005). Once the moving party satisfies its burden, the non-moving party must, in rebuttal, present sufficient evidence of a genuine issue, in rebuttal. Santini v. Fuentes, 795 F.3d 410, 416 (3d Cir. 2015). The

court must then resolve all doubts as to the existence of a genuine issue of material fact in favor of the non-moving party. Saldana v. Kmart Corp, 260 F.3d 228, 232 (3d Cir. 2001). Summary judgment is appropriate if the non-moving party provides merely colorable, conclusory or speculative evidence. Anderson, 477 U.S. at 249. There must be more than a scintilla of evidence supporting the non-moving party and more than some metaphysical doubt as to the material facts. Id. at 252. Unsubstantiated arguments made in briefs are not considered evidence of asserted facts. Versarge v. Twp. of Clinton, 984 F.2d 1359, 1370 (3d Cir. 1993). Moreover, "a party resisting a [Rule 56] motion cannot expect to rely merely upon bare assertions, conclusory allegations or suspicions." Gans v. Mundy, 762 F.2d 338, 241 (3d Cir. 1985) (citing Ness v. Marshall, 660 F.2d 517, 519 (3d Cir. 1981)).

## III. MOTION FOR SUMMARY JUDGMENT ON DIRECT INFRINGEMENT

### A. Facts Relating to Direct Infringement

The following facts are derived from the evidence submitted by the parties in support and opposition to summary judgment. Where there is conflicting evidence about a particular fact, Federal Rule of Civil Procedure 56 requires that I view all facts and evidence in the light most favorable to Plaintiffs. [1]

Plaintiff accuses Defendant's products of direct infringement. Defendant seeks summary judgment on the direct infringement claims relating to the '913 patent and the '022 patent.

Claim 1 of the '913 patent recites:

[1] References to the parties' pleadings will be made as follows: Defendant's Statement of Undisputed Facts ("DSUF"); Plaintiff's Response ("PR"), Plaintiff's Additional Statement of Facts ("PASF"), and Defendant's Response ("DR"). To the extent a statement is undisputed by the parties, I will cite only to the parties' submissions. If a statement is disputed and the dispute can be easily resolved by reference to the exhibits, I will cite the supporting exhibits. If a statement is disputed, but the dispute cannot be resolved by reference to the exhibits, I will note the disputed fact. I will not rely on any statement of fact that is unsupported by reference to a specific exhibit.

> A tool for manipulating and inserting a universal, intervertebral bone fusion spacer into a disc space between a first vertebral body and a second vertebral body for providing fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, wherein the universal, intervertebral bone fusion spacer includes an intervertebral cage having a first integral screw guide and a second integral screw guide, wherein each longitudinal end of the intervertebral cage includes a slot or indentation formed adjacent to an edge of an upper surface of the intervertebral cage, the tool comprising:
>
> a gripper having a plurality of prongs,
>
> wherein a distal end of each of the plurality of prongs is capable of engaging a respective slot or indentation of the intervertebral cage; and
>
> a screw guide for controlling a direction of screws that are inserted into the first integral screw guide and the second integral screw guide,
>
> wherein the screw guide is positioned between the plurality of prongs.

(DSUF ¶ 1; PR ¶ 1.)[2]

Asserted claim 47 of the '022 Patent states:

> A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:
>
> an intervertebral cage including;
>
> a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;
>
> an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at

[2] Asserted claim 10 of the '913 Patent depends from claim 1 and shares its preamble. (DSUF ¶ 2; PR ¶ 2.)

> least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;
>
> a second integral screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and
>
> a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

(DSUF ¶ 3; PR ¶ 3.)[3]

In my August 25, 2021 claim construction order, I construed the term "universal"—as used in both Patents—to mean "an intervertebral bone fusion spacer designed to be inserted between [vertebrae/vertebral bodies] in any region of the spine, *i.e.*, cervical, thoracic, or lumbar, using any approach, *e.g.*, posterior, anterior, or lateral." (ECF No. 144, p.1). Based on that claim construction, Plaintiff concedes that none of the products accused of infringing the '022 and '913 Patents are "universal." (DSUF ¶ 7; PR ¶ 7.)

Plaintiff's expert neurosurgeon, William Rosenberg, has opined that certain of Defendant's products—specifically the COALITION, COALITION AGX, HEDRON IC, and INDEPENDENCE products—infringe claims 1 and 10 of the '913 Patent. (Pl.'s Ex. 1, Decl. of William Rosenberg ("Rosenberg Decl.") ¶ 6.) Dr. Rosenberg has also opined that certain of Defendant's products infringe the '022 Patent. (Rosenberg Decl., Ex. B ("Rosenberg Dep.") ¶ 63; Def.'s Ex. 2, Expert Report of Michael C. Sherman ("Sherman Rep.") ¶ 4.) Plaintiff agrees that

[3] Claim 58 of the '022 Patent depends from claim 47 and shares its preamble. (DSUF ¶ 4; PR ¶ 4.)

the accused products are not "universal" under the Court's construction but nonetheless presses that because the term "universal" appears only in the preambles of claims 1 and 10 of the '913 Patent and claim 47 of the '022 Patent, it is not limiting on those patents.

**B. Analysis of Direct Infringement**

"Generally, . . . the preamble does not limit the claims." Am. Med. Sys, Inc. v. Biolitec, Inc., 618 F.3d 1354, 1358 (Fed. Cir. 2010) (quotations omitted). Nonetheless, "it is not unusual . . . to treat preamble language as limiting." Bicon v. Strauman Co., 441 F.3d 945, 952 (Fed. Cir. 2006). Whether to treat a preamble as a limitation is a determination "resolved only on review of the entire[] . . . patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

"In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning and vitality' to the claim." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999)). Thus, where preamble terms "give meaning to the claim and properly define the invention," the preamble is considered limiting. Bausch & Lomb Inc. v. Moria S.A., 222 F. Supp. 2d 616, 648 (E.D. Pa. 2002); see also Pitney Bowes, 182 F.3d at 1306 (where "term can only be understood in context of preamble statement," preamble is limiting). Conversely, a preamble is not regarded as limiting "when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention," or where a patentee uses the preamble only to state a purpose or intended use of the invention. Catalina Mktg., 289 F.3d at 809; Bicon, Inc., 441 F.3d at 952.

"No litmus test defines when a preamble limits claim scope," but the Federal Circuit has identified several "guideposts" to assist in the determination. Catalina Mktg., 289 F.3d at 808. Primarily, "dependence on a particular disputed preamble phrase for antecedent basis" or the need for the preamble "to understand limitations or terms in the claim body" may indicate that the preamble limits claim scope because it demonstrates a "reliance on both the preamble and the claim body to define the claimed invention." Id.; see Gen. Elec. Co. v. Ninetendo Co., Ltd., 179 F.3d 1350, 1361 (Fed. Cir. 1999) (preamble reading a "system for displaying a pattern on a raster scanned display device by mapping bits from a display location in a member associated with a computer onto the raster" was incorporated by reference because of language in claim and was held to be limiting for breathing life and meaning into claim).

In addition, "when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation." Catalina Mktg, 289 F.3d at 808; see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989) (finding preamble limiting where the patent's specification clarified that inventors were working on a particular problem in optical communications and, without preamble language, claim would "indiscriminately cover all types of optical fibers," which would be "divorced from reality").

"[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." Catalina Mktg., 289 F.3d at 808. Absent such reliance, the preamble is generally not limiting, so long as the claim body describes a structurally complete invention, such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention. Id. at 809.

Finally, preambles that merely describe the use of an invention or give an intended purpose "generally do not limit the claims because the patentability of apparatus or composition depends on the claimed structure, not on the use or purpose of that structure." Id. This is because the "inventor of a machine is entitled to the benefit of all the uses to which it can be put, no matter whether he had conceived the idea of the use or not." Id. (quoting Roberts v. Ryers, 91 U.S. 150, 157 (1875)).

In particular, when dealing with apparatus claims—such as the claims at issue here—construction is "governed by the well-established principle that '[a]pparatus claims cover what a device *is*, not what a device *does*.'" Eli Lilly & Co v. Teva Pharms Int'l GmbH, 8 F.4th 1331, 1340 (Fed. Cir. 2021) (quoting Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1468 (Fed. Cir 1990)). For claims directed to apparatuses or compositions, the Federal Circuit has "often relied on the proposition that '[p]reamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim.'" Id. (quoting Bicon, 441 F.3d at 952); see, e.g., Cochlear Bone Anchored Solutions AB v. Oticon Med. AB, 958 F.3d 1348, 1355 (Fed. Cir. 2020) (holding that a statement of intended purpose in the preamble—"for rehabilitation of unilateral hearing loss"—was not limiting because the claimed apparatus (a hearing aid) was fully structurally claimed in the body of the claim, and its structure would allow it to function identically whether or not used for its stated intended purpose); TomTom, Inc. v. Adolph, 790 F.3d 1315, 1324 (Fed. Cir. 2015) (noting language stating a purpose or intended use tends to employ the standard pattern of such language: "a method for a purpose or intended use comprising" followed by the body of the claim.).[4] "Even with respect to

[4] See, e.g., STX, LLC v. Brine, Inc., 211 F.3d 588, 591 (Fed. Cir. 2000) (preamble phrase "which provides improved playing and handling characteristics" followed by claim that was "self-contained description that could stand alone, with or without the preamble" held to be non-limiting preamble."); Bristol-Myers Squibb Co. v. Ben Venue Lab., Inc., 246 F.3d 1368, 1375–76 (Fed.

apparatus or composition claims, however, [the Federal Circuit has], when warranted by the facts, found statements of intended purpose to be limiting." Eli Lilly, 8 F.4th at 1341.

Applying these "guideposts" here, I find that the preambles at issue are limiting for several reasons.

First, as noted above, where terms in the preamble provide an antecedent basis for the same terms in the body of the claim, there is a "strong indication that the preamble acts 'as a necessary component of the claimed invention.'" Bio-Rad Labs., Inc. v. 10X Genomics Inc., 967 F.3d 1353, 1371 (Fed. Cir. 2020) (quotation omitted); see also In re Fought, 941 F.3d 1175, 1178. "In patent law, it is widely understood that the recitation of the term 'the' or 'said' before a feature [in the body of the claim] indicates to a reader that the feature following these terms has been introduced prior in the claim language." In re Ciprodex, No. 15-cv-5756, 2017 WL 2784410, at *8 (D.N.J. June 27, 2017). "[A]s such, recitation of 'the' or 'said' feature simply indicates that a new feature is not being introduced in the claim" and that reference to an earlier cited feature is necessary. Id.

For both of the patents-in-suit, the claim language depends on the preamble phrase for an antecedent basis and uses the term "the" before a feature in the body of the claim, such that the preamble is essential to understanding the limitations or terms in the claim body. The claim body of Claim 1 of the '913 Patent, *without* the preamble, recites:

Cir. 2001) (preamble reading a "method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" held to be a statement of purpose that failed to result in a "manipulative difference in the steps of the claim").

> the tool comprising:
>
> a gripper having a plurality of prongs,
>
> wherein a distal end of each of the plurality of prongs is capable of engaging a respective slot or indentation of ***the*** intervertebral cage; and
>
> a screw guide for controlling a direction of screws that are inserted into ***the*** first integral screw guide and ***the*** second integral screw guide,
>
> wherein the screw guide is positioned between the plurality of prongs.

('913 patent, claim 1 (emphasis added).) Read in isolation from the preamble, the claim references a gripper tool with (a) a plurality of prongs that can be used to engage some type of slot on "the" intervertebral cage and (b) a screw guide for controlling the direction of screws "the" integral screw guides. The claim language does not, however, answer any questions about the nature, location, and design of "the intervertebral" cage, the slot or indentation on such cage, or "the integral screw guides" with which the claimed "tool" is designed to work. Without reference to the preamble, the claimed tool is structurally incomplete in that it is unclear what type of slot or indentation the prongs on the gripper must be designed to engage, where the screw guides need to be placed, or how they are to be designed so that the tool can control the screws' direction.

The preamble resolves those questions by describing an intervertebral cage that is part of the "universal, intervertebral bone fusion spacer." That cage has a "slot or indentation" on each longitudinal end, which is "formed adjacent to an edge of an upper surface of the intervertebral cage." In addition, the preamble clarifies that the tool must be capable of controlling screws that go into "the" first integral screw guide and "the" second integral screw guide, which are included in "the" intervertebral cage and allow for the insertion of the universal bone fusion disc spacer.

By referencing "the intervertebral cage" and "the integral screw guide," the claim effectively incorporates by reference the description of those terms within the preamble.

Second, I disagree with Plaintiff's position that the *entirety* of the preamble—particularly the part containing the term "universal"—is not limiting because none of the terms in the body reference the phrase "universal, intervertebral combination internal screw guide fixation apparatus." Plaintiff points out that the claim's body language describes only "[a] tool" that can manipulate and insert the universal, intervertebral bone fusion spacer to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion. Thus, according to Plaintiff, the portion of the preamble using the term "universal" constitutes language stating a purpose or intended use and thus cannot be construed as limiting.

In support of this position, Plaintiff relies on C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340 (Fed. Cir. 1998), wherein the patent claimed:

> A biopsy needle for use with a tissue sampling device having a housing with a forward end, a first slide mounted for longitudinal motion within said housing, and a second slide mounted for longitudinal motion within said housing, said biopsy needle comprising:
>
> a hollow first needle having proximal and distal ends;
>
> a second needle extending through said hollow first needle and freely slidable therewithin, said second needle having proximal and distal ends;
>
> a first head mounted to said proximal end of said hollow first needle, said first head including first flange means associated therewith for coupling said hollow first needle to said first slide for longitudinal motion both toward and away from said forward end of said housing; and
>
> a second head mounted to said proximal end of said second needle, said second head including second flange means associated therewith for coupling said second needle to said second slide for

> longitudinal motion both toward and away from said forward end of said housing.

Id. at 1348–49. The Federal Circuit found that the preamble's recitation of the portion and structure of the gun housing into which the claimed needles fit was not limiting because the claimed patent only referred to the needles not the gun. Id. at 1350. The Court determined that the description of the housing defined the intended function of the needles that were the subject of the claim. Id.

In contrast to Bard, the Federal Circuit in Bicon, Inc. v. Straumann Co., 441 F.3d 945 (Fed. Cir. 2006) found a preamble to be limiting for a patent which claimed an apparatus used with dental implants. The patent in suit described a plastic cuff designed to preserve a space around a dental implant so that when a crown was placed on top of the implant, the base of the crown fit beneath the patient's gum line. Id. at 946. The preamble of the claim recited elements pertaining to the structure of the "abutment" used with the claimed emergence cuff. Id. at 952. Distinguishing Bard, the Court noted that the preamble language in Bard merely described what the claimed needle was for (coupling to the structure in the preamble), but the plain language of the claim did not require an actual coupling to this structure. Id. at 953. With respect to the patent before it, however, the preamble language was limiting because "[d]espite the fact that the claim beg[an] with a reference to the emergence cuff alone, the full text of the claim, read in context of the entire patent, indicated that the claimed invention is the combination of the emergence cuff and the abutment, operating together in the fashion recited in the claim and described in the specification." Id. at 952; see also Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1340–42 (Fed. Cir. 2003) (distinguishing Bard and finding that preamble was limiting where the manipulation and operation of the structure described by the preamble gave meaning and purpose to the manipulative steps of the claim).

Cognizant that the Federal Court has generally been "disinclined to sanction finding a preamble 'partially' limiting by splicing it," Bio-Rad Labs., 967 F.3d at 1371, I find that the claim at issue is more akin to Bicon than Bard. The tool identified in claim 1 of the '913 Patent only has "life, meaning, and vitality" when read in conjunction with all of the preamble language. The claim language does not just refer to any gripper with prongs and a screw guide, but rather one that is capable of manipulating and inserting "a universal, intervertebral bone fusion spacer" into a disc space by engaging a certain slot or indentation of the intervertebral cage and controlling the direction of screws into the screw guides contained on that intervertebral cage. In other words, the claimed tool, the bone fusion spacer, and the intervertebral cage are interlocking items operating together in the fashion recited in the claim. The tool's use with the spacer and cage is not a preferred or intended use; rather it is the precise use of which the tool must be capable. Like in Bicon, the detailed description in the preamble is necessary to define the structure of the claimed device.

This rationale applies equally, if not more so, to asserted claim 47 of the '022 Patent, which describes the "intervertebral cage." As noted above, claim 47 states:

> A universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion, the apparatus comprising:
>
> an intervertebral cage including;
>
> a top wall, a bottom wall, and two sidewalls defining an open space capable of receiving bone filling for the biological bone fusion;
>
> an internal screw guide having an internal bore with an entry opening and an exit opening, the entry opening of the internal bore formed only in a top surface of the top wall and the exit opening formed at least partially in a bottom surface of the top wall and at

> least partially in a side surface of the top wall, wherein the internal screw guide further includes a counterbore that is larger than and coaxial with internal bore and has a counterbore entry opening that is formed only in the top surface of the top wall;
>
> a second integral screw guide having a second internal bore with a second entry opening and a second exit opening, the second entry opening of the second internal bore formed only in the top surface of the top wall and the second exit opening formed at least partially in the bottom surface of the top wall and at least partially in a second side surface of the top wall; and
>
> a circular hole extending through the top wall in a direction substantially normal to the top surface of the top wall, wherein the circular hole is positioned between the internal screw guide and the second internal screw guide at the top surface of the top wall.

Although Plaintiff contends that the body of claim 47 of the '022 patent defines a structurally complete "intervertebral cage," closer scrutiny reveals that the claim language actually discloses an "apparatus comprising" an intervertebral cage with (a) a top wall, bottom wall, and two sidewalls; (b) an internal screw guide; (c) a second internal screw guide; and (d) a circular hole extending through the top wall. By referring to "the apparatus," the claim necessarily seeks an antecedent basis in the preamble language, which discloses "[a] universal, intervertebral combination internal screw guide and fixation apparatus configured to be inserted into a disc space between a first vertebral body and a second vertebral body and to provide fusion of the first vertebral body to the second vertebral body via biological bone fusion and screw fusion." In other words, the invention is not merely any intervertebral cage with the indicated specifications and without any requirement as to the cage's function. Rather, the invention includes the entire "universal, intervertebral combination internal screw guide and fixation apparatus," which has the capabilities defined by the preamble. And like claim 1 of the '913 patent, the preamble language is not merely an intended use; rather it defines the claimed invention itself.

Third, guidance in the specifications of the patents also supports the conclusion that the preambles limit the claims. "[A] preamble may be construed as limiting when it recites particular structure or steps that are highlighted as important by the specification." Proveris Sci. Corp. v. Innovasystems, Inc., 739 F.3d 1367, 1372 (Fed. Cir. 2014). For example, in Proveris, the claim at issue read:

> An apparatus for producing image data representative of at least one sequential set of images of a spray plume, each of the images being representative of a density characteristic of the spray plume (i) along a geometric plane that intersects the spray plume, and (ii) at a predetermined instant in time, comprising:
>
> > an illuminator for providing an illumination of the spray plume along at least one geometric plane that intersects the spray plume; and,
> >
> > an imaging device for generating the image data representative of an interaction between the illumination and the spray plume along the at least one geometric plane.

Id. at 1372. In determining whether the preamble was limiting, the Federal Circuit noted that he specification identified the invention as producing a "sequential set of images" and focused on the ability of the invention to capture "the time evolution of the spray." Id. at 1373. The Court determined that the preamble was the only reference in the claim language to the inventive concept of capturing a sequence of images in order to characterize the time evolution of the spray plume. Id. The Court held that "[t]his fact alone is likely sufficient to support a conclusion that the preamble is limiting." Id. (citing Deere & Co. v. Bush Hog, LLC, 703 F.3d 1349, 1358 (Fed. Cir. 2012) (finding that preamble phrase "rotary cutter deck" was a limitation where the specification referred to "the present invention" as a "rotary cutter deck"); Poly-Am., LP v. GSE Lining Tech., Inc., 383 F.3d 1303, 1310 (Fed. Cir. 2004) (construing preamble as limiting where it disclosed a "fundamental characteristic of the claimed invention")).

Here, the "Background of the Invention" section of both the '913 patent and the '022 patent indicates that the invention relates to a "unique universal bidirectional screw (BDS) system, and in particular its application to the spine, also referred to as bi-directional fixating transvertebral (BDFT) screws which can be used as a stand-alone intervertebral device which combines the dual function of an intervertebral spacer which can be filled with bone fusion material(s), as well as a transvertebral bone fusion screw apparatus." ('913 patent, col. 1, lines 28–35; '022 patent, col. 1 lines 32–40.) Throughout both specifications, the inventors describe the invention as possible for use in the various regions of the spine and through various approaches, and they specifically discuss an "expandable embodiment of the screw box [that] can also be enlarged and modified to be suitable for cervical, thoracic and lumb[a]r vertebral body replacements." (See, e.g., '913 patent col. 3, lines 41–43; '022 patent, col. 3, lines 52–54.)

Yet, when reaching the claim language itself, the body of claim 1 of the '913 patent references only a gripper tool with both a plurality of prongs that can engage a slot on an intervertebral cage and a screw guide for controlling a direction of screws. The body of claim 47 of the '022 patent references an apparatus with an intervertebral cage that has four walls capable of receiving bone filling, two integral screw guides, and a circular hole through the top wall. The preamble of both patents contains the only claim language capturing the "unique universal bidirectional screw (BDS) system" and its application to the spine. Absent the limitations provided by the preamble, the body of the claims fails to capture a fundamental characteristic of the claimed invention.

Finally, I address the parties' arguments during the claim construction process. The effect of preamble language is a claim construction issue. Cochlear Bone Anchored Solutions AB v. Oticon Med. AB, 958 F.3d 1348, 1354 (Fed. Cir. 2020). District courts may engage in

"rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1361 (Fed. Cir. 2002). Moreover, a party is not judicially estopped from asserting a different claim construction position so long as the positions are not "irreconcilably inconsistent" and the change was not done in bad faith. Merck Sharp & Dohme Corp. v. Xellia Pharms. ApS, No. 14-cv-199, 2015 WL 82386 (D. Del. Jan. 6, 2015).

Plaintiff's arguments during claim construction, however, are instructive as to its own understanding as to the importance and function of the preamble. Specifically, throughout claim construction briefing, arguments made during the Markman hearing, and in a motion for clarification, Plaintiff—albeit urging a different construction of the term "universal"—clearly emphasized that "universal" was a limiting term, asserting:

- "[T]he '022 and '913 patents teach that the invention is 'universal' in the sense that it 'can be used as a stand-alone intervertebral device which combines the dual functions of an intervertebral spacer . . . as well as a transverterbral bone fusion screw apparatus.'" (Pl.'s Opening Cl. Constr. Br., ECF No. 117, p. 7)

- "The patent specification makes abundantly clear that 'universal' in this context refers to the stand-alone, dual-use (spacer and bone fusion screw apparatus) functionality of the claimed bidirectional screw system." (Id. at p. 9.)

- "The intrinsic evidence shows that 'universal' in the context of the ['913 and '022 patents] means the invention supports the dual functions of an intervertebral spacer and intervertebral bone fusion screw apparatus . . . In this way, the stand-alone device is more versatile than a device that must be compatible with other specific devices." (Pl.'s Resp. Cl. Constr. Br., ECF No. 123, p. 2.)

- "The idea of Moskowitz's invention was to – was to try to preclude that by having a – that's the sense of the term universal, as used here. We have one device that has dual functionality." (Tr. Cl. Constr. Hrg. 28:10–13.)

- "The parties genuinely dispute the proper interpretation of the Court's construction of 'universal' as it relates to the '913 and '022 patents. Resolution of this dispute affects the infringement and validity issues for the '913 and '022 patents." (Pl.'s Mot. for Clarification, ECF No. 162, p. 9.)

- "Not only will resolution of this dispute [over the meaning of the term 'universal'] save considerable judicial and party resources, it is legally required." (Pl.'s Reply, ECF No. 190, p. 1.)

- "[Defendant's] opposition also fails to rebut the critical fact that its interpretation [of 'universal'] would exclude each and every embodiment disclosed in the '913 and '022 patents from the scope of the claims." (Id. at 1–2.)

These repeated statements made by Plaintiff, in various contexts, that the '913 and '022 patents claim a "universal" invention reinforces my finding that the preamble of both patents is indeed limiting.[5]

Having determined that the preambles of both claim 1 of the '913 patent and claim 47 of the '022 patent are limiting, I now consider whether Defendant is entitled to summary judgment of noninfringement. "When an accused infringer moves for summary judgment of noninfringement, such relief may be granted only if at least one limitation of the claim in question does not read on an element of the accused product, either literally or under the doctrine of equivalents." M2M Solutions LLC v. Enfora, Inc., 167 F. Supp. 3d 665, 672 (D. Del. 2016) (citing Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1376 (Fed. Cir. 2005); TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1369 (Fed. Cir. 2002) ("Summary judgment of noninfringement is . . . appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.")). "'Thus, summary judgment of non-infringement can only be granted if, after viewing the alleged facts in the light most favorable to the non-movant, there is no genuine issue as to whether' the accused

[5] Defendant also argues that, during IPR proceedings for the '913 and '022 Patents, Plaintiff repeatedly relied on the preamble to distinguish the claimed invention over the prior art. While statements made by a patent owner during an IPR proceeding can be considered during claim construction and relied upon to support a finding of prosecution disclaimer, the statements used to invoke the doctrine of prosecution disclaimer must "be both clear and unmistakable." Aylus Networks, Inc. v. Apple, Inc., 856 F.3d 1353, 1359 (Fed. Cir. 2017). Having reviewed the IPR proceedings in this case, I decline to determine whether Plaintiff made any "clear and unmistakable" statements that the term "universal is limiting.

product is covered by the claims as construed by the court." Id. (quoting Pitney Bowes, Inc. v. Hewlett–Packard Co., 182 F.3d 1298, 1304 (Fed. Cir. 1999)).

Under this standard, I find, as a matter of law, that Defendant is entitled to summary judgment on Plaintiff's claims of direct infringement of the '022 and '913 patents. "Universal" is a limiting term for both the '022 and '913 patents. Plaintiff has expressly stated that it "does not dispute that none of the products accused of infringing the '022 and '913 patents is 'universal' as construed by the Court." (PR ¶ 7.) Given this concession and its clear impact on the infringement issue, Defendant cannot, as a matter of law, be liable for infringement.

## III. MOTION FOR SUMMARY JUDGMENT ON INDIRECT INFRINGEMENT UNDER 35 U.S.C. § 271(b)

### A. Facts Relating to Indirect Infringement

Plaintiff contends that Defendant induced infringement of the '022 patent, the '268 patent, the '319 patent, the '913 patent, the '740 patent, and the '643 patent by providing materials to surgeons—including Surgical Technique Guides, Product Overviews, and through internal sales force presentations—all of which teach surgeons specifically how to use their accused products. Plaintiff posits that for the accused products that do not necessarily infringe on one of Plaintiff's patents, Defendant's written materials and Defendant's sales force presentations teach surgeons to use the products in an infringing manner.

Each of the accused products has a Surgical Technique Guide, which is a document that provides step-by-step guidance for surgeons with respect to how to surgically insert the spinal implant. (Pl.'s Ex. 3, Rule 30(b)(6) Dep. of Archana Bhat ("Bhat Dep.") 54:9–21.) The Surgical Technique Guides for the alleged infringing products list the instruments that are available in the instrument set. (DSUF ¶ 8; PR ¶ 8.)

One of the instruments included in the accused products' instrument set is a "drill guide" ("DTS") which is used with Defendant's INDEPENDENCE implants and COALITION implants that works with the drill tap and screw instruments. (Def.'s Ex. 20, Rule 30(b)(6) Dep. of Colm McLaughlin ("McLaughlin 30(b)(6) Dep.") 223:6–9.) According to Defendant, the drill guide tool is not *always* used with the INDEPENDENCE and COALITION implants, and there are other options. (Id. at 223:10–24.) Defendant's representative testified that the drill guide tool could, in theory, be removed from the INDEPENDENCE and COALITION sets. (Id. at 224:1–4; see also Def.'s Ex. 14 at Globus-Mosk–00122 (noting that for COALITION instrumentation, "[s]elf-centering instruments ensure proper trajectory without the use of DTS guides.").) Indeed, in 2012, Defendant removed the DTS from certain consigned instrument sets because it was rarely used by surgeons. (Def.'s Ex. 14, Report of Michael Sherman ("Sherman Rep.") ¶ 171 (DTS Guide has "an estimated use in the field of less than 10% of the cases."); Def.'s Ex. 21, Def.'s Rule 30(b)(6) Dep. of Christy Mace ("Mace 30(b)(6) Dep."), 222:11–18.)

According to Plaintiff, however, the insertion tool for each of the accused products is designed to work with the corresponding implant and vice versa. (Rosenberg Rep. ¶¶ 106, 112, 114, 120.) Although the Surgical Technique Guides for at least the COALITION, INDEPENDENCE, and MAGNIFY-S products describe different insertion instruments that a surgeon can choose to use during surgery (Def.'s Exs. 14, 18, 19), Dr. Rosenberg opined that for several of the accused products, surgeons do not have the ability to choose between more than one insertion tool. (Rosenberg Rep. ¶¶ 106, 112, 114, 120.)

Defendant also contends that it does not sell the accused product tools to hospitals. Rather, its sales representatives and distributors "generally maintain custody of the tools, and typically provide the tools to the customer as needed when there is a procedure." (Def.'s Ex. 22, Resp. to

Interrog. No. 2, at 6.) Defendant notes that there are a few instances in which hospitals store or consign the tools. (Id.) Defendant does acknowledge that there "may be instances" in which Defendant sells a set to the hospital directly. (Bhat Dep. 316:8–19.)

The parties agree that the Surgical Technique Guides for at least some of the accused products describe different anchor and screw configurations and different endplate configurations that a surgeon can use during surgery, some of which may be infringing. (DSUF ¶¶ 13–14; PR ¶¶ 13–14.) The Surgical Technique Guides may be provided either prior to the sale of the product or after the sale has been made to assist the surgeon with actual surgery. (Bhat Dep. 55:5–13.) Defendant's sales representative could either send a copy of the Surgical Technique Guides remotely or physically hand a hard copy to the surgeon. (Id. at 55:15–24.) In addition, Defendant's sales representatives are commonly at the hospitals and interacting in person with the surgeons and may be present at the surgery to answer any questions depending on the experience level of the surgeon. (Id. at 56: 1–57:4.) The Surgical Technique Guides are typically reviewed with the surgeon prior to the surgery, but in some cases, if the surgeon is familiar with the device or the procedure, he or she may not need the review. (Id. at 57:15–24.)

Each Surgical Technique Guide is imprinted with a disclaimer that states:

> The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depend on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

(Def.'s Ex. 14; DSUF ¶ 16; PR ¶ 16.)

Defendant also publishes a "Product Overview" for each product that is available to Defendant's sales representatives before the product launches. Each Product Overview is imprinted with a disclaimer that states: "Confidential and proprietary. Do not distribute. This material is for informational purposes only and is intended only for Globus Medical employees and representatives." Defendant does not distribute Product Overview documents directly to hospitals or surgeons. (Def.'s Ex. 24; DSUF ¶ 17; PR ¶ 17.)

**B. Analysis of Indirect Infringement Claims**

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To demonstrate inducement of infringement, the patentee must establish, first, that there has been direct infringement, and second, that the alleged infringer had "knowledge that the induced acts constitute patent infringement." Global–Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011). "Inducement requires evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct infringer's activities." DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1306 (Fed. Cir. 2006).

Defendant seeks summary judgment on Plaintiff's induced infringement claim, arguing that Plaintiff has pointed to insufficient evidence to prove either direct infringement by a third party or intent to induce infringement.

1. Evidence of Direct Infringement by Defendant's Customers

*a. The '740, '643, and '913 patents*

Under the first element of an induced infringement claim, a plaintiff must show that a third party directly infringed the asserted claims. Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1322 (Fed. Cir. 2009). A showing of direct infringement by a third party requires *either* a finding

that the accused products necessarily infringe—*i.e.*, that there are no substantial non-infringing uses of a product—or a finding of specific instances of direct infringement by third parties. ACCO Brands, Inc. v. ABA Locks Mfrs. Co., 501 F.3d 1307, 1313 (Fed. Cir. 2007). "On multiple occasions, the Federal Circuit has held that circumstantial evidence is sufficient to support a jury verdict of indirect infringement, both with respect to the element of inducement and the element of direct infringement by the induced party." IOENGINE, LLC v. PayPal Holdings, Inc., Nos. 18-cv-452, 18-cv-826, 2022 WL 2800861, at *19 (D. Del. June 15, 2022) (collecting Federal Circuit cases). Circumstantial evidence, however, "must show that at least one person directly infringed an asserted claim during the relevant time period." Toshiba Corp. v. Imation Corp., 681 F.3d 1358, 1364 (Fed. Cir. 2012) (citing Lucent Techs., 580 F.3d at 1317).

The Federal Circuit illustrated the operation of this principle in ACCO Brands, Inc. v. ABA Locks Mfrs. Co., Ltd., 501 F.3d 1307 (Fed. Cir. 2007). There, the plaintiff brought an action against its competitor defendant alleging direct and induced infringement of a patent directed toward locking systems that inhibited theft of equipment such as personal computers. Id. at 1310. In support of its induced infringement claim, the plaintiff argued that a set of instructions in defendant's product described the infringing method, and it pointed to expert testimony that the infringing use was the "natural and intuitive way to employ the device." Id. at 1312. Plaintiff asserted that the jury was entitled to accept the expert's testimony and find that, at least some of the time, all users of defendant's product would use it in an infringing manner. Id. at 1312. The Federal Circuit rejected this argument noting that the accused device could be operated in both an infringing and in a non-infringing manner, meaning that "the accused device does not necessarily infringe" the patent in suit. Id. at 1313. The Court noted that the plaintiff had not pointed to specific instances of direct infringement, the sole testimony on using the lock in an infringing

manner was plaintiff's expert, and "the record contain[ed] no evidence of actual users having operated the lock in an infringing manner." Id. Based on its determination that the record lacked substantial evidence to support a finding of direct infringement, the Federal Circuit reversed the jury verdict of inducement. Id. at 1314; see also SRI Int'l Inc.v. Internet Sec. Sys., Inc., 647 F. Supp. 2d 323, 338 (D. Del. 2009) (finding no indirect infringement where accused products did not "necessarily infringe" the patents and, at trial, the plaintiff did not present any witness testimony of any of defendant's employees or its actual customers demonstrating that direct infringement occurred).

Here, it is undisputed that the '740, '643, and '913 patents do not "necessarily infringe" because Defendant does not sell pre-assembled systems that necessarily infringe the asserted claims. Rather, Defendant makes implant and instrument sets available to surgeons prior to surgery, and the surgeon chooses, based on his/her experience and skill, which instruments to use with which implant. The Surgical Technique Guides provided by Defendant for the instrument sets products describe different configurations of implants and instruments that a surgeon can use during surgery. Some of the configurations are alleged to infringe the asserted claims, while others are not.

Because there is no dispute that the accused products have non-infringing uses, the accused products do not "necessarily infringe" and Plaintiff must point to specific instances of direct infringement. According to Defendant, Plaintiff has not produced testimony from a single surgeon showing that he/she used Defendant's products in an infringing manner. Defendant contends that the absence of such evidence is crucial because if Plaintiff's documents actually encouraged its customers to infringe, infringement would not be an isolated incident and Plaintiff would be able to adduce evidence of at least one example of actual infringement. See Lucent Techs., Inc., 543

F.3d at 723 (finding no error in court's analysis that if using the infringing combination of software was "so common and routine, then certainly [plaintiff] could have produced evidence of at least one instance" where infringement occurred."). Defendant notes that Dr. Rosenberg, Plaintiff's expert, himself testified that he did not refer to Surgical Technique Guides during surgery and did not rely on sales representatives to teach him how to perform the procedure. (Def.'s Ex. 1, Rosenberg Dep., 32:18–33:10.) Defendant also presses that, Plaintiff did not perform any user surveys or studies to show that all surgeons necessarily used the accused products in an infringing manner. (Id. at 29:10–14.)

Defendant's argument, however, disregards the principle that a plaintiff need not specifically identify third-party infringers. Rather, it is well established that a party may present "circumstantial evidence that some party committed direct infringement of the asserted method claims by using the accused product." O2 Micro Int'l Ltd. v. Beyond innovation Tech. Co. Ltd., 449 F. App'x 923, 928 (Fed Cir. 2011); see, e.g., i4i Ltd. Partnership v. Microsoft Corp., 598 F.3d 831, 852 (Fed. Cir. 2010) ("Evidence that consumers were using Word in an infringing manner included Microsoft data on usage of Word, as well as a Microsoft marketing document listing 'real' examples of custom XML's use in Word."); Arthrocare Corp. v. Smith & Nephew, Inc., 406 F.3d 1365, 1377 (Fed. Cir. 2005) (finding sufficient circumstantial evidence of direct infringement showing that accused products were used in an infringing manner including admissions by the defendant's expert, videotapes of electrosurgeries during which accused product was used, and an admission by project managers for two of the accused products that the products were used in an infringing manner); Malibu Boats, LLC v. Skier's Choice, Inc., 534 F. Supp. 3d 888, 904 (E.D. Tenn. 2021) (finding that defendant's materials and published videos showing boats with surf

systems practicing the patented methods sufficient to create a jury question of whether there was direct infringement by third parties).

While Plaintiff concedes that it has not identified any particular surgeon who used the accused products in an infringing manner, Plaintiff points to several pieces of evidence that it claims shows specific instances of direct infringement for each of the three patents:

- **'740 Patent:** For the accused product to infringe the '740 patent, at least two anchors must be used during surgery. Plaintiff identifies a Defendant-produced spreadsheet for some of the accused products identifying the "anchor unit usage per surgery," showing over $32 million in revenue associated with surgeries where surgeons used more than two anchors. (Pl.'s Ex. 8.) Such revenue information reflects usage because Defendant invoices the surgeon's hospital based on an order form created after surgery, and sales reps then then fill out "usage reports." (Pl.'s Ex. 9, Rule 30(b)(6) Dep. of Robert Miller ("Miller Dep."), 158:9–159:21; Pl's Ex. 3, Bhat Dep. 144:6–145:12.)

- **'643 Patent:** For the accused product to infringe the '643 patent, the accused product must have endplates with spikes or screws to infringe. Plaintiff identifies a Defendant-produced spreadsheet showing usage data for "spike constructs," which indicates approximately $8 million in revenue where surgeons used the infringing "spike construct[]" configuration. (Pl.'s Ex. 12, Supp. Resp. to Interrog. No. 17.) Again, the revenue information equates with actual usage. (Miller Dep. 158:9–159:21; Bhat Dep. 144:6–145:12.)

- **'913 Patent:** The '913 patent is directed to an insertion tool. Plaintiff concedes that surgeons have the option to insert implants using the accused implant/drill guide insertion tool or the non-accused laterally holder, but notes that Defendant's corporate witness and Defendant's expert both stated that there is at least some minimal (approximately ten percent) usage of the accused tool for inserting implants. (Pl.'s Ex. 13, Rule 30(b)(6) Dep. of Christy Mace ("Mace Dep.") 219:3–11; Pl's Ex. 14, Expert Rep. of Michael Sherman ("Sherman Rep.") ¶ 171.)

Defendant challenges the sufficiency of this evidence, arguing that (a) Plaintiff has failed to connect Defendant's conduct/marketing materials to these various usages and (b) the evidence shows that non-infringing sales account for at least half of the usage, and a showing that a tool is used in an infringing manner less than 10% of the time is insufficient to support an induced infringement claim.

While Defendant's responses may be highly persuasive to a factfinder, I conclude they are insufficient to justify granting summary judgment. First, Defendant cites to no authority for the proposition that, to prove direct infringement, a plaintiff must connect the reasons for the infringing use with the defendant's conduct. Indeed, the Federal Circuit has emphasized that "where an alleged infringer designs a product for use in an infringing way and instructs users to use the product in an infringing way, there is sufficient evidence for a jury to find direct infringement." Toshiba, 681 F.3d at 1365. The Federal Circuit has "affirmed induced infringement verdicts based on circumstantial evidence of inducement (*e.g.*, advertisements, user manuals) directed to a class of direct infringers (*e.g.*, customers, end users) without requiring hard proof that any individual third-party direct infringer was actually persuaded to infringe by that material." Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc., 843 F.3d 1315, 1335 (Fed. Cir. 2016).

As to Defendant's second argument, it is well established that "a finding of infringement can rest on as little as one instance of the claimed method being performed during the pertinent time period." Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1317 (Fed. Cir. 2009); see also Toshiba Corp., 681 F.3d at 1364. As such, the mere fact that the infringing use of the accused product is less common than the non-infringing uses is of no moment.[6]

[6] Defendant's cited cases are inapposite. See Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1323 (Fed. Cir. 2009) (reversing jury finding of active inducement where accused device did not necessarily infringe and no reasonable jury could find that a purchaser of the accused device who followed the accompanying instructions would have used the device in an infringing manner); MBO Labs., Inc. v. Becton, Dickinson & Co., No. 03-cv-10038, 2011 WL 1740711, at *3–4 (D. Mass. May 6, 2011) (cursorily noting that the plaintiff failed to provide any admissible evidence that any acts of direct infringement occurred); Minsurg Int'l Inc. v. Fronter Devices, No. 10-cv-1589, 2011 WL 486120, at *3–4 (M.D. Fl. Feb. 7, 2011) (noting that because the plaintiff failed to provide any "substantial evidence" that surgeons have used any of the defendant's products in an infringing manner, induced infringement claim could not survive).

In short, Plaintiff's evidence—while not identifying by name particular surgeons who used the products in an infringing fashion—does create an issue of fact as to whether the accused products were actually being used in an infringing manner. This evidence, taken as true, may be sufficient to support a jury's finding that at least one surgeon or other end user used the accused products in an infringing way. In turn, a jury could reasonably find direct infringement by a third party.

*b. The '022, '268, and '319 patents*

In its opening brief in support of its Motion for Partial Summary Judgment, Defendant argued that it was seeking summary judgment on the induced infringement claims as to all of the asserted patents. In doing so, it discussed these patents as a group without parsing out individual proof for each patent and without demonstrating substantial non-infringing uses for any specific accused product.

In response, Plaintiff contends that for the remaining three patents—the '022, '268, and '319 patents—there are no non-infringing configurations of the accused products and, thus, they necessarily infringe. Plaintiff details evidence of how the claims of each of these three patents have no non-infringing uses, such that every use of the accused products constitutes an act of direct infringement. (Pl.'s Opp'n Summ. J. 15–18.) Plaintiff also references the report of its expert, William Rosenberg, who opines that there are no non-infringing uses of the accused products for any of these three patents. (Pl.'s Ex. 1, Decl. of William Rosenberg ("Rosenberg Decl."), Ex. B ("Rosenberg Rep.") ¶¶ 106, 114, 130.) Only in its reply brief does Defendant cite to excerpts from the report of its own expert, Michael Sherman, who reaches the opposite conclusion that the accused products have substantial non-infringing uses. (See Def.'s Reply Br. 8 (citing Def. Ex. 2, Sherman Rep. at pp. 66, 104, 115.)

Despite bearing the burden of proving its entitlement to summary judgment, Defendant offers little briefing on this issue and presents only its expert report, which conflicts with Plaintiff's expert report. Based on the limited information before me, I cannot determine whether the accused products for the '022, '268, and '319 patents have substantial non-infringing configurations such that Plaintiff would have to produce evidence of direct infringement. Accordingly, I find that, for purposes of Plaintiff's induced infringement claim regarding these three patents, a genuine issue of material fact remains as to direct infringement.

2. Specific Intent to Induce Infringement

As noted above, to establish liability under § 271(b), a patent holder must also prove that "once the defendants knew of the patent, they 'actively and *knowingly* aid[ed] and abet[ed] another's direct infringement.'" DSU Med. Corp. v. JMS Col., Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (quoting Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1998) (emphasis in original)). The mere knowledge of possible infringement by others is not enough; rather specific intent and action to induce infringement must be proven. Id. (quotations omitted). As clarified by the Federal Circuit:

> It must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Manville, 917 F.2d at 553. In short, inducement requires a showing that the alleged inducer knew of the patent, knowingly induced the infringing acts, and possessed a specific intent to encourage another's infringement of the patent. DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1304 (Fed. Cir. 2006) (en banc in relevant part). Intent can be shown by circumstantial evidence, but the mere knowledge of possible infringement will not suffice. Id. at 1305–06.

Here, Defendant contends that it is entitled to summary judgment on the inducement of infringement claims because Plaintiff has not shown that Defendant had a specific intent to induce infringement. Specifically, it argues that: (1) liability cannot be predicted on acts that occurred before Defendant had notice of the patent, and (2) there is no evidence that Defendant encouraged, recommended, or promoted use of its implants and instruments in an infringing manner.

*a. Pre-notice Activity*

Defendant first contends that it cannot be liable because it created the Surgical Technique Guides, Product Overviews, and internal sales force training materials for each of the accused products *before* the issue date of five of the six asserted patents. According to Defendant, the FDA requires Defendant to develop the Surgical Technique Guides before it launches a product on the market. Therefore, Defendant contends that, as a matter of law, these materials are not valid evidence of a specific intent to induce infringement for five of the six patents in this case, given that they were not developed at a time that Defendant had knowledge of the asserted patents.

"Evidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that that infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd., 545 U.S. 913, 936 (2005) (internal quotations omitted). Although advertising and technical support for infringing products can constitute evidence of intent to induce infringement, such marketing activities are not sufficient unless such activities are coupled with actual knowledge of the patents-in-suit and awareness that the accused products infringe the patents-in-suit. ReefEdge Networks, LLC v. Juniper Networks, Inc., 29 F. Supp. 3d 455, 459 (D. Del. 2014). As such, the Federal Circuit has

emphasized that, as a matter of law, affirmative acts taken before a patent issues cannot violate § 271(b). GlaxoSmithKline LLC v. Teva Pharms USA, Inc., 7 F.4th 1320, 1337 (Fed. Cir. 2021).

When, however, a defendant begins an action before a patent issues and then continues to take that action after the patent issues, with intent to cause third parties to directly infringe, a jury can find that the requisite intent exists. Id. at 1337–38 (holding that a jury could infer from defendant's placement of information on its website—information that was taken from pre-patent press releases—that defendant intended its website to be a source of information for prescribing doctors and that its website promoted the infringing use throughout the period of infringement); Barry v. Medtronic, Inc., 914 F.3d 1310, 1336 (Fed. Cir. 2019) (evidence that, after plaintiff's patents issued, defendant's sales force provided training materials to doctors and was constantly teaching surgeons the nuances of and techniques for using the accused devices was sufficient for jury to find induced infringement, even though the accused products were on the market for years before the patents-in-suit issued).

Plaintiff emphasizes that it is not relying solely on Defendant's one-time creation of the referenced materials, such as Surgical Technique Guides, for evidence of inducement. Rather, Plaintiff relies on Defendant's post-issuance conduct, including its "continuous and systematic marketing campaign in which its sales force team distributes technique guides to surgeons and performs product demos to encourage surgeons to use the accused products." (Def.'s Opp'n Summ. J. 21.) In particular, Plaintiff cites the following evidence:

- Defendant's Rule 30(b)(6) witness Dr. Bhat, testified that the purpose of the surgical technique guides is to instruct the surgeons on how to use the implant, and the guides "are typically reviewed with the surgeon prior to the surgery." (Bhat Dep. 57:15–24, 205:13–25.) Plaintiff has produced evidence that surgeons used the accused products after the patents issued. (Miller Dep. 158:9–159:21.)

- Defendant's sales force representatives conduct product demos for surgeons, and other of Defendant personnel provide cadaver labs showing surgeons how to insert the products. (Bhat Dep. 136:22–137:9; 147:14–148:1, 273:15–274:17.)

- Defendant's Product Overview documents teach sales force representatives how to provide a "successful demo" for surgeons and direct representatives to "[u]se samples to highlight ease of anchor insertion, anchor removal, and accompanying Anchor Removal Tool." (Pl.'s Ex. 17, at GLOBUS-MOSK_00028911.)

- Plaintiff's expert Dr. Rosenberg notes that Defendant disseminates brochures and other marketing materials and also maintains a website called MERC academy, which provides events such as symposiums, educational courses, and cadaver labs instructing surgeons how to use the accused products according to the surgical techniques described in the technique guides and training and product demonstration videos. (Rosenberg Rep. ¶ 141.)

Such evidence, if believed by a jury, could support a finding that that Defendant intended to induce infringement subsequent to learning about Plaintiff's patents.

*b. Evidence that Defendant "Encouraged" Surgeons to Infringe*

Alternatively, Defendant contends that the record "fails to show that [Defendant] encouraged, recommended, or promoted use of its implants and instruments in an infringing matter." (Pl.'s Mot. Summ. J. 24.) Defendant asserts that the Surgical Technique Guides merely describe various combinations of implants and instruments that a surgeon could use to perform spinal fusion surgery, and that some of the combinations allegedly infringe while others do not. According to Defendant, Plaintiff fails to show that Defendant's instructions to surgeons evince the requisite *mens rea* and *scienter*.

"[P]roof of actual intent to cause the acts which constitute the infringement is a necessary prerequisite to finding active inducement." Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990); see also DSU Med. Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1306 (Fed. Cir. 2006). As noted above, "[e]vidence of active steps taken to encourage direct infringement such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe, and a showing that that

infringement was encouraged overcomes the law's reluctance to find liability when a defendant merely sells a commercial product suitable for some lawful use." Metro-Goldwyn-Mayer, 545 U.S. at 936. Notably, a patentee may prove intent to induce infringement by circumstantial evidence and "[t]he drawing of inferences, particularly in respect of an intent-implicating question . . . is peculiarly within the provision of the fact finder that observed the witnesses." Broadcom Corp. v. Qualcomm Inc., 543 F.3d 683, 700 (Fed. Cir. 2008) (quoting Rolls-Royce Ltd. v. GTE Valeron Corp., 800 F.2d 1101, 1110 (Fed. Cir. 1986)).

Defendant contends that Plaintiff cites to no evidence that surgeons regularly received and reviewed the Surgical Technique Guides or any other of Defendant's materials before or during surgery. Defendant further notes that Plaintiff's own expert, who was a practicing surgeon for more than two techniques, testified that he did not review Surgical Technique Guides either during or in advance of surgery to select which products to use. In addition, Defendant claims that Plaintiff has adduced no evidence of what Defendant's sales force representatives orally communicate and physically demonstrate to surgeons, such that a jury could infer intent to induce infringement.

Plaintiff responds, that for the accused products of at least three of the patents—the '022, '268, and '319 patents—there is only one possible configuration a surgeon must use, and those configurations necessarily infringe. Plaintiff reasons that Defendant has a "sales force" team to disseminate the Sales Technique Guides and promotional materials and to conduct demos to convince surgeons to use its products. (Bhat Dep. 25:23–27:7.) As such, it presses that there is sufficient evidence of encouragement.

As to the remaining patents—the '740, '643, and '913 patents—Plaintiff again concedes that the accused products have both infringing and non-infringing configurations. Nonetheless,

Plaintiff points to evidence that Defendant instructs its sales representatives to teach use of the accused products in an infringing manner, and advertises that the "two-anchor" configuration of one of the products is "less invasive" in contrast to the non-infringing configuration. (Pl.'s Ex. 17 at GLOBUS-MOS_00028913; Ex. 18 at GLOBUS-MOSK_00000237; Ex. 19 at GLOBUS-MOSK_000290072.) As this evidence suggests that accused products were "capable of infringing" and Defendant's representatives actively taught some of these infringing configurations to surgeons, a jury could find that Defendant designed the products to be used in an infringing way and purposefully instructed users to use them in the infringing way through its sales force presentations. At minimum, such evidence is sufficient to create a genuine issue of fact and preclude summary judgment. [7]

## IV. CONCLUSION

In light of the foregoing, I will grant summary judgment in favor of Defendant with respect to Plaintiff's direct infringement claims relating to the '913 patent and the '022 patent. As to Plaintiff's claims of induced infringement, I find that a genuine issue of material fact remains regarding whether there was direct infringement by third parties and whether Defendant possessed the requisite intent to induce infringement. An appropriate Order follows.

---

[7] Defendant's cited cases are inapposite. In Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1329 & n.2 (Fed. Cir. 2009), the Federal Circuit found that the original product instructions did not evidence a specific intent to encourage infringement since they taught a "stirring action" which the defendant could have reasonably believed was non-infringing. In addition, the amended product instructions taught an undisputedly non-infringing use and the product design naturally encouraged a non-infringing use, evidencing intent to *discourage* infringement. Id. at 1329. By contrast here, Plaintiff presents evidence that the Surgical Technique Guides taught infringing uses and that Defendant's sales representatives were directed to teach surgeons to use the accused products in an infringing manner, evidencing an intent to *encourage* infringement.

In ACCO Brands,Inc. v. ABA Locks Mfrs. Co., Ltd., 501 F.3d 1307 (Fed. Cir. 2007), the Federal Circuit determined that there was no evidence of direct infringement and, therefore, never reached the issue of whether there was evidence of intent to induce infringement. Id. at 1314.